UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C.R. Bard, INC., PELVIC SYSTEM Products Liability Litigation	**MDL No. 2187**

This Document Relates To:

Vickie G. McCloskey, et al. v. C.R. Bard, Inc. **No. 14-cv-03784**

PLAINTIFF VICKIE G. MCCLOSKEY'S RESPONSE IN OPPOSITION TO THE MOTION OF C.R. BARD, INC. FOR PARTIAL SUMMARY JUDGMENT AS TO PLAINTIFFS WHOSE CLAIMS ARE GOVERNED BY INDIANA LAW

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PRELIMINARY STATEMENT

Plaintiff Vickie G. McCloskey ("Plaintiff") respectfully submits this Response in Opposition to the Motion of Defendant C.R. Bard Inc. ("Defendant") for Partial Summary Judgment as to Plaintiffs Whose Claims Are Governed by Indiana Law. Defendant has filed a motion for partial summary judgment against multiple plaintiffs whose claims, it contends, arise under Indiana law. Plaintiff will respond only to those sections and arguments that are directed at her case specifically.

Plaintiff alleges claims for: (I) Negligence; (II) Strict Liability—Design Defect; (III) Strict Liability—Manufacturing Defect; (IV) Strict Liability—Failure to Warn; (V) Breach of Express Warranty; (VI) Breach of Implied Warranty; and (VIII) Punitive Damages.

Plaintiff does not intend to pursue, and therefore does not object to the dismissal of Claims V and VI for breach of warranty.

ARGUMENT[1]

I. PLAINTIFF'S CLAIMS ARE NOT TIME-BARRED

A. The Applicable Legal Standards

Indiana's two-year statute of limitations for personal injury begins "to run from the date the plaintiff knew or should have discovered that she suffered an injury or impingement, and that it was caused by the product or act of another." *Barnes v. A.H. Robins Co.*, 476 N.E. 2d 84, 87-88 (Ind. 1985). The issue is generally one of fact for the jury. *Degussa Corp. v. Mullens*, 744 N.E. 2d 407, 411 (Ind. 2001), *quoting Van Dusen v. Stotts*, 712 N.E.2d 491, 499 (Ind. 1999). The issue "*may* become a matter of law" if, for example, "a plaintiff's doctor expressly informs the plaintiff that there is a 'reasonable possibility, if not a probability' that an injury was caused by an act or product. *Id*. (emphasis added). Even when a doctor has discussed mesh complications with a

[1] Plaintiff does not dispute that the issues raised in Defendant's motion are governed by the law of Indiana.

patient, however, the issue may remain one of fact for the jury. *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6886129, at *4 (S.D.W. Va. Nov. 24, 2014) ("I cannot determine as a matter of law that [plaintiff] discovered her cause of action more than two years before filing suit.") Defendant does not contend that Plaintiff was put on inquiry notice by any doctor's diagnosis such as to possibly cause the statute of limitations to run as a matter of law.

Although events short of a doctor's diagnosis can provide a plaintiff with evidence of a reasonable possibility that another's product caused his or her injuries, "a plaintiff's mere suspicion or speculation that another's product caused the injuries is insufficient to trigger the statute." *Id*. Whether events short of a doctor's diagnosis are sufficient to cause the statute to begin to run presents an issue of fact for the jury. *Id*.

In *In re: Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp.2d 1348 (M.D. Ga. 2010), the defendant argued – much like Defendant argues here – that each of the three plaintiffs suffered cognizable injuries and had mesh removal surgeries more than two years before their suits were filed, which it contended should bar their claims. The court, however, concluded that genuine issues of material fact were presented because the types of injuries suffered by the plaintiffs were those associated with implantable mesh product, which they were warned about, and none of the plaintiffs' doctors had ever told them their products might be defective. *Id., followed in Carr v. Ethicon, Inc.*, 2011 WL 4424457 (N.D. Ga. 2011) (denying summary judgment even though plaintiff had mesh removal surgery more than two years prior to filing suit). *See also Aebischer v. Stryker Corp.*, 535 F.3d 732 (7th Cir. 2008) (applying analogous discovery rule under Illinois law; reversing trial court's grant of summary judgment and noting that whether plaintiff's failure to suspect a product defect was reasonable under the circumstances may turn on when physician seriously considered possibility of a product defect and whether he communicated those suspicions, which was an issue for jury).

B. The Record Presents an Issue of Fact for Trial Regarding When Plaintiff Knew or Should Have Known That Her Injuries Were Caused by Defendant's Defective Product

Plaintiff was implanted with an Align to treat her SUI on December 29, 2009. She filed her Complaint on January 22, 2014. Pursuant to Pretrial Order Numbers 80 and 99, however, her claims were tolled on July 3, 2013, so her complaint is deemed to have been filed on that date.

In support of its motion, Defendant focuses on Plaintiff's testimony that she "attributed" her injuries to its product soon after her surgery in 2010, more than two years before her case was filed. (Defendant's Exhibit 3 at 94:10-95:22) Defendant, however, completely disregards the second step in the analysis, which is to show that Plaintiff knew or should have known that the product was defective at that time.

Not only did Plaintiff not know that the mesh was defective more than two years before she sued, she was actually assured by her implanting physician, William Shirrell, M.D., in December 2012 – less than two years before the period of limitations was tolled – that the mesh was not causing any of her problems.

> Q· ·I'm going to hand you what's been marked as Exhibit 17.· Do you recognize this document?
> A· ·Yes.
> Q· ·What is this document?
> A· ·Again, this is a recapitulation of my office visit with her on [December 20, 2012].
> Q· ·What happened on this visit?
> A· ·Again, it sounds as though she's still having a lot of abdominal and pelvic discomfort.· She's developed, you know, pain with intercourse to a point where she has vaginal bleeding afterwards.
> Q· ·You'll see about midway through the first paragraph there, it says, "Her concern of this relates to her Align midurethral graft that she has in place.· She is almost fixated on the concept that this is the source of all of her somatic problems."
> Do you see that?
> A· ·Yes.
> Q· ·What do you recall her telling you about that?

A· ·I don't know that I have a great deal of recollection of what she voiced other than the fact it sounds like she was very much associating her problems with the graft that she has in place.
Q· ·Do you know how it is that she became fixated on the concept that the Align was the source of all of her problems?
A· ·No, I do not.
Q· ·And when you say "somatic problems," what do you mean?
A· ·Well, just systemic problems.· Pain and problems away from the area where her graft was located.
Q· ·Did you share her concern that her somatic symptoms were related to the Align?
A· ·No.· *I told her I didn't think they were related at all*.

(Ex. 2 108:6-109:17 (emphasis added))

Thus, while Defendant may have *suspected* that the mesh was causing her problems, she was assured by her doctor that her problems were completely unrelated to the mesh. And, of course, there is no evidence that her doctor told her the mesh (which was supposedly not causing her problems in any event) was *defective*. Dr. Shirrell certainly would not have told her the mesh was defective, since he still considers it the standard of care. (Ex. 3 at 20:12-21:4)[2]

It was not until months later, after she saw TV advertising and contacted attorneys, that she first learned that Dr. Shirrell had implanted Defendant's defective mesh.[3] On this record, there is an issue of fact for trial regarding when the statute of limitations was triggered.

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[2] No doctor ever told Plaintiff before she contacted her attorneys that her mesh was causing her problems, much less that the mesh was defective. (Ex. 3 at 37:17-19; 53:25-55:16; 69:14-20; 214:16-24; 243:7-9) Furthermore, Plaintiff did not even know which mesh device Dr. Shirrell had implanted. (Ex. 3 at 89:6-8; 271:3-14)

[3] Plaintiff testified that she contacted her lawyers a few weeks after she saw the TV ads. Although she testified that she did not recall when that happened, she also testified that it happened in 2010. (Ex. 3 at 24:19-26:18) According to her attorneys' records, however, she contacted them for the first time on April 30, 2013. (Affidavit of Andrew S. Williams, sworn to January 23, 2015 at ¶ 6) Her counsel did not attempt to correct the deposition testimony on cross examination, because he did not know that that time that the testimony was inaccurate. (*Id*. at ¶ 4) Defendant does not rely on Plaintiff's demonstrably inaccurate recollection.

II. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT ON THE FAILURE TO WARN CLAIMS SHOULD BE DENIED

"Whether a manufacturer has discharged its duty under the sophisticated intermediary doctrine is almost always a question for the trier of fact." *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 164 (Ind. Ct. App. 1997) Under Indiana law, there are numerous factors for the trier of fact to consider, including the likelihood that harm will occur if the intermediary does not pass on the warning to the ultimate user, the nature of the probable harm, the probability that the particular intermediary will not pass on the warning, the ease or burden of the giving of the warning by the manufacturer to the ultimate user, whether the intermediary had knowledge or sophistication equal to that of the manufacturer or supplier, and whether it was reasonable for the manufacturer to rely on the intermediary to warn the ultimate consumer. *Id*. Reliance is only reasonable if the intermediary knows or should know of the product's dangers. *Id*.

Defendant largely ignores the many factors that must be considered in order to establish the learned intermediary defense, and if focuses entirely on the argument that, according to Defendant, there is no evidence that Plaintiff's implanting physician, Dr. William Shirrell, would have acted differently in prescribing the Align based on different information in a way that would have prevented Mrs. McCloskey from receiving it.

The question for the trier of fact under the learned intermediary exception is *not* whether an adequate warning would have caused the learned intermediary to recommend a different device or procedure. Rather, the question is whether, if the learned intermediary had received adequate warnings, he might have provided different information to his patient and whether the patient might have made a different decision if she had been provided with that different information. *See*, e.g., *Toole v. McClintock*, 999 F.2d 1430, 1433 (11th Cir. 1993) (in affirming the denial of directed verdict, applying Alabama's learned intermediary doctrine and finding that "a different warning . . . would have caused [the physician] to behave differently" where a reasonable juror could conclude

that "a different warning would have caused [the physician] to warn [the patient]"); *Kirchman v. Novartis Pharm. Corp.*, No. 8:06-CV-1787-T-24, 2014 WL 2158519, at *5 (M.D. Fla. May 23, 2014); *Guenther v. Novartis Pharm. Corp*., 990 F. Supp. 2d 1299 (M.D. Fla. Feb. 20, 2014) (denying Rule 50(a) motion on proximate cause issue under Florida law where there was sufficient evidence that a different warning could have prevented the plaintiff's injury by "prompting the physician to pass along a more detailed warning"); *Daniel v. Wyeth Pharm., Inc*., 15 A.3d 909, 925 (Pa. Super. 2011) (Pennsylvania law); *Gilliland v. Novartis Pharm. Corp*., No. 1:12-CV-00029, 2014 WL 3747175, at *9 (S.D. Iowa July 25, 2014) (Iowa law).[4]

Thus, while it may be true that Dr. Shirrell continues to implant Align slings today and would recommended it today to treat Mrs. McCloskey, that does not resolve the question whether he would have provided Mrs. McCloskey with the same information today that he did in 2009 had he been given different warnings.

While Dr. Shirrell testified that he has not changed his discussion of the risks associated with Align that he has with patients since 2009, that does not mean that he would not have changed his discussion of risks if he had been provided with adequate warnings. Defendant makes much of the fact that Plaintiff did not cross examine Dr. Shirrell on this issue. Because the learned intermediary doctrine is an "exception" to the general rule that a manufacturer must provide warnings to the consumer directly, and because it is considered a "defense," *Natural Gas Odorizing*, 685 N.E.2d at 163, the burden should be on Defendant to prove that defense by proving that Dr. Shirrell would not have changed his warnings, even if he had known what Defendant knew about the risks of chronic pain, chronic dyspareunia, urinary urgency, and increased frequency of urination. Defendant has not met that burden.

[4] Plaintiff has not found any Indiana case that addressed this issue. Plaintiff submits that the Indiana courts, if confronted with the issue, would follow the well-reasoned authorities cited here.

Furthermore, Dr. Sherrell testified that he *does* do something differently today: he gives his patients a copy of the January 3, 2014 AUGS/SUFU statement. While that statement supports the use of polypropylene suburethral slings for SUI, it also informs the reader that there is a "mesh controversy," "fear," and "litigation" concerning the safety of the product. (Ex. 4 at 1, 3). It also conspicuously fails to mention a single complication associated with the product. When it mentions the FDA's 2013 notice, it refers to "clinical trials that followed patients for *up to one-year*." (Ex. 4 at 2 (emphasis added)) Notwithstanding AUGS/SUFS's supportive conclusion, any reasonable woman, reading that statement, is likely to have grave reservations about the wisdom of having such a controversial and relatively untested device permanently implanted in her vagina.

Accordingly, Defendant's motion for summary judgment on its learned intermediary defense should be denied.

III. PLAINTIFFS DO NOT INTEND TO PURSUE A SEPARATE CLAIM FOR "MANUFACTURING DEFECT"

In light of the Court's consistent rulings across these pelvic mesh MDLs as to manufacturing defect, Plaintiff does not intend to pursue a separate claim for "manufacturing defect," as such claim has been construed by the Court (not manufactured in accordance with design, or departure from manufacturer's design specifications). *E.g., Cisson. v. C.R. Bard, Inc.*, No. 2:11-cv-00195, Dkt. No. 272, slip op. at 8 (S.D. W.Va. June 4, 2013) (Georgia law); *Tyree v. Boston Scientific Corp.*, Case 2:12-cv-08633, Dkt. No. 446, slip op. at 5-6 (S.D. W.Va. Oct. 17, 2014).

In support of Plaintiff's negligence, failure to warn, and punitive damages claims, however, Plaintiff does intend to present evidence that Defendant's manufacturing process and the raw materials used in the manufacture of Defendant's products resulted in defects in the product, which is consistent with the Court's prior rulings. *E.g., Cisson* at 8. By not contesting Defendant's motion as to "manufacturing defect," Plaintiff does not forego, waive or in any way agree that any

evidence relating to Defendant's manufacturing process and raw materials are restricted in any way.

IV. PLAINTIFFS ARE NOT ASSERTING DISTINCT CLAIMS FOR NEGLIGENT INSPECTION, MARKETING, LABELING, PACKAGING OR SELLING

Defendant's motion seeks judgment as a matter of law on what it refers to as Plaintiffs' "claims" for "negligent inspection, marketing, labeling, packaging, and selling." In support of its argument on these negligence claims, Bard urges that Plaintiffs either have not pursued such "claims," or else that these "claims" should fail due to lack of evidence. Bard thus plainly misconstrues the nature of Plaintiffs' claims set forth in Count I of their Complaint. Because Plaintiffs are not asserting distinct claims under the various subcategories as defined in Bard's motion, its motion is misguided, and should be denied. Count I of Plaintiffs' Master Long Form Complaint sounds generally in negligence. As Bard consistently recognizes across its state-specific motions, the law throughout this country is that negligence involves a duty, breach of that duty, causation and damages. Contrary to the assertion of Bard's motion, Plaintiffs do not attempt to allege separate and distinct claims, each standing alone, of "negligent inspection," "negligent marketing, "negligent labeling," "negligent packaging" and "negligent selling." Instead, all of these aspects are part of Plaintiffs' general negligence claim in these cases, as set forth in Count I of the Master Long Form Complaint.

In each of the several bellwether cases tried in this pelvic mesh litigation pending before this Court, the juries have been charged generally on negligence – not on any sub-category of negligence. In each of these Wave 1 and 2 cases, Plaintiffs submit that the jury will be charged generally on negligence. The jury will not be charged on "negligent inspection/marketing/labeling/packaging/selling" in any case.

Bard's contention that Plaintiffs have not adduced evidence of negligence in these cases is simply contrary to fact. Evidence of Bard's negligence, including negligence relating to its

marketing of its products, its failure to properly test and study its products, and its negligence relating to the design of its products and its defective accompanying warnings was presented to the jury in the *Cisson* bellwether trial, and the jury returned a verdict for compensatory and punitive damages in favor of the Plaintiffs there. Plaintiffs are separately responding to Bard's motion for summary judgment as to punitive damages, and therein Plaintiffs cite to an abundance of testimonial and documentary evidence that likewise bears directly on this motion. Rather than recite the same evidence again, and in the interests of convenience and economy, Plaintiffs hereby incorporate their separate response to Bard's motion for summary judgment as to punitive damages in its entirety.

Plaintiffs have demonstrated Bard's failure to adequately study or test these products to determine their safety for permanent human implantation prior to selling them for implantation in women's bodies throughout the world. While Bard and its experts have repeatedly alleged that Bard conducted so-called "industry standard" ISO "biocompatibility testing" on these products to argue the reasonableness of its conduct, the facts show that Bard did not perform full ISO biocompatibility testing on these products, and instead deliberately chose not to do so. Bard has also argued that its "bench testing" or "materials characterization testing" supports its reasonableness. However, this Court has held in this MDL and in the related Boston Scientific MDL, these laboratory tests involving pulling or pushing on mesh with machinery do nothing to demonstrate how materials will behave in the body, and thus are irrelevant to the question of whether these products were safe to be implanted permanently in the female pelvis. Bard conducted limited animal implantation studies prior to the launch of these products, but the results of these studies were overwhelmingly negative; the biomaterials engineer hired by Bard to conduct these studies to determine whether the products were safe for implantation testified that she could not make any such conclusion from her studies.

Plaintiffs have proven that Bard negligently failed to conduct clinical studies in spite of repeated requests from its employees and outside advisors that human studies were needed. One of Bard's Research and Development engineers said in an internal Bard communication that no testing was "par for the course" for Bard. Bard was negligent in failing to adequately study and test these products before allowing them to be implanted in these Plaintiffs.

In Bard's motions in limine filed in the initial bellwether process in this MDL, Bard moved to exclude any evidence that Bard had had or breached an independent duty to conduct testing or inspection of its products. *Cisson*, C.A. No. 2:11-cv-00195, Dkt. No. 268, p. 41 (Bard Motion in Limine No. 4 – "Motion to Preclude any Evidence or Argument that Bard Owed or Breached an Independent Duty to Conduct Additional Testing or Inspection"). The Court declined to exclude this evidence, holding that while Plaintiffs' Complaint did not contain a separate claim for "negligent failure to test," or "negligent inspection," "evidence regarding Bard's testing or inspection generally, or lack thereof, may be relevant to whether Bard 'knew or should have known' of the alleged dangers in the Avaulta products. It is highly probable that the admissibility of such evidence or argument depends on the context and method by which the plaintiffs seek to introduce them. *Cisson*, C.A. No. 2:11-cv-00195, Dkt. No. 302, p. 6 (Memorandum Opinion and Order – Parties' Motions in Limine). The Court subsequently recognized in *Cisson* that evidence of Bard's failure to adequately test its products also goes to the design defect risk/utility analysis, as well as to the question of punitive damages. *Cisson*, C.A. No. 2:11-cv-00195, Dkt. No. 356 (Memorandum Opinion and Order – Plaintiffs' Motion for Clarification on the Court's Ruling on Bard's Failure to Test, and for a Ruling on Bard's Objections to Evidence that Bard Claims "Implies Bard had a Duty to Conduct Clinical Trials or Additional Testing). This motion for summary judgment is nothing more than a motion in limine in disguise – the same sort of motion

the Court has already considered and decided. The same rationale applies to Bard's present motion, and warrants its denial.

Plaintiffs have demonstrated that Bard knew that its products were unreasonably dangerous and defective, and that complications were being caused by the specific design features of these products, but Bard made no efforts to correct known defects, and continued to sell these products to be permanently implanted in women worldwide. Bard was negligent in selling and marketing these products in spite of its knowledge that the products posed unreasonable risks to patients.

The facts also demonstrate Bard's negligence in labeling and packaging of these products, which includes its warnings and instructions. Plaintiffs have produced evidence that Bard's warnings and instructions sold with these products were deficient, and failed to provide information to physicians and patients regarding known risks and the frequency, severity, duration and extent of complications known to be associated with these products. To the contrary, Bard's instructions said that the "[p]otential adverse reactions are those typically associated with surgically implantable materials," thus intentionally understating the risks that it knew were associated specifically with these products. Bard's warnings and instructions also negligently failed to instruct physicians how to properly implant these devices so as to minimize the potential for known complications.

As with Bard's claims regarding negligent testing/inspection, this summary judgment motion is nothing more than an improper attempt to limit proper and relevant evidence bearing on Plaintiffs' claims of negligence, design defect, failure to warn, and punitive damages. In Bard's motions in limine filed in the initial bellwether process in this MDL, Bard moved to exclude any evidence that Bard had a duty to train physicians. *Cisson*, C.A. No. 2:11-cv-00195, Dkt. No. 268, p. 41 (Bard Motion in Limine No. 13 – "Motion to Preclude any Evidence or Argument that…Bard Owed or Breached a Duty to Train Plaintiffs' Physicians"). The Court declined to exclude this

evidence, holding that while Plaintiffs' Complaint did not contain a separate claim for "negligent training," "it is highly probable that the admissibility of evidence or argument regarding training depends on the context and method by which the plaintiffs seek to introduce them." *Cisson*, C.A. No. 2:11-cv-00195, Dkt. No. 302, p. 8 (Memorandum Opinion and Order – Parties' Motions in Limine). Plaintiffs should not be prohibited or limited in their evidence based on Bard's attempt by way of this summary judgment motion to parse Plaintiffs' negligence claim into minutae.

Bard's conduct in marketing, selling, labeling, and testing of these products goes directly to Plaintiffs' negligence claim in general, as well as to Plaintiffs' claims relating to design, warnings, and punitive damages. Bard's effort to compartmentalize Plaintiffs' negligence claim into discrete subsets is clearly a backdoor effort to try and set up its ability to argue for the exclusion of evidence at trial, and is legally unfounded. Bard's contention that Plaintiffs have not presented any evidence of its negligence is simply not supported by the record. Bard's motion on Plaintiffs' negligence claim should be denied.

V. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AS TO PUNITIVE DAMAGES SHOULD BE DENIED

In support of its motion in these cases, Defendant incorporates by reference its separate motion for partial summary judgment on all Plaintiffs' claims for punitive damages. In response, therefore, Plaintiff respectfully incorporates by reference Plaintiffs' response in opposition to Defendant's separate motion.

VI. PLAINTIFFS' ADOPT THE ARGUMENTS OF OTHER PLAINTIFFS

To the extent they are material to the motion addressed to Plaintiffs, Plaintiff respectfully adopts the arguments offered by the plaintiffs in the other cases that are the subject of Defendant's motion.

CONCLUSION

Defendant's motion should be denied.

Dated: January 26, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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